

Introduced by Senator Battin

February 16, 2005

An act to amend Section 125290.30 of the Health and Safety Code, relating to stem cells.

LEGISLATIVE COUNSEL'S DIGEST

SB 340, as introduced, Battin. Stem cell research: revenues.

The California Stem Cell Research and Cures Act, an initiative measure, establishes the California Institute for Regenerative Medicine, the purpose of which is, among other things, to make grants and loans for stem cell research, for research facilities, and for other vital research opportunities to realize therapies, protocols, and medical procedures that will result in the cure for, or substantial mitigation of, diseases and injuries. Existing law establishes the Independent Citizen's Oversight Committee (ICOC), composed of appointed members, that is required to perform various functions and duties with regard to the operation of the institute.

Existing law requires the ICOC to establish standards that require that all grants and loan awards be subject to intellectual property agreements that balance the opportunity of the State of California to benefit from the patents, royalties, and licenses that result from basic research, therapy development, and clinical trials with the need to assure that essential medical research is not unreasonably hindered by the intellectual property agreements. Existing law provides for the payment to the state of patent royalties and license revenues but is silent regarding into which fund this money is to be deposited.

Existing law also provides that the General Fund consists of money received into the State Treasury and not required by law to be credited to any other fund.

This bill would require that all revenues derived from patents, royalties, and licenses paid to the state as a result of intellectual property agreements entered into pursuant to these provisions be deposited into the General Fund.

Vote: majority. Appropriation: no. Fiscal committee: no.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. The Legislature finds and declares that this act
2 supplements, and does not amend, the California Stem Cell
3 Research and Cures Act, enacted by Proposition 71 at the
4 November 2, 2004, General Election.

5 SEC. 2. Section 125290.30 of the Health and Safety Code is
6 amended to read:

7 125290.30. Public and Financial Accountability Standards

8 (a) Annual Public Report

9 The institute shall issue an annual report to the public which
10 sets forth its activities, grants awarded, grants in progress,
11 research accomplishments, and future program directions. Each
12 annual report shall include, but not be limited to, the following:
13 the number and dollar amounts of research and facilities grants;
14 the grantees for the prior year; the institute's administrative
15 expenses; an assessment of the availability of funding for stem
16 cell research from sources other than the institute; a summary of
17 research findings, including promising new research areas; an
18 assessment of the relationship between the institute's grants and
19 the overall strategy of its research program; and a report of the
20 institute's strategic research and financial plans.

21 (b) Independent Financial Audit for Review by State
22 Controller

23 The institute shall annually commission an independent
24 financial audit of its activities from a certified public accounting
25 firm, which shall be provided to the State Controller, who shall
26 review the audit and annually issue a public report of that review.

27 (c) Citizen's Financial Accountability Oversight Committee

28 There shall be a Citizen's Financial Accountability Oversight
29 Committee chaired by the State Controller. This committee shall
30 review the annual financial audit, the State Controller's report
31 and evaluation of that audit, and the financial practices of the

1 institute. The State Controller, the State Treasurer, the President
2 pro Tempore of the Senate, the Speaker of the Assembly, and the
3 Chairperson of the ICOC shall each appoint a public member of
4 the committee. Committee members shall have medical
5 backgrounds and knowledge of relevant financial matters. The
6 committee shall provide recommendations on the institute's
7 financial practices and performance. The State Controller shall
8 provide staff support. The committee shall hold a public meeting,
9 with appropriate notice, and with a formal public comment
10 period. The committee shall evaluate public comments and
11 include appropriate summaries in its annual report. The ICOC
12 shall provide funds for the per diem expenses of the committee
13 members and for publication of the annual report.

14 (d) Public Meeting Laws

15 (1) The ICOC shall hold at least two public meetings per year,
16 one of which will be designated as the institute's annual meeting.
17 The ICOC may hold additional meetings as it determines are
18 necessary or appropriate.

19 (2) The Bagley-Keene Open Meeting Act, Article 9
20 (commencing with Section 11120) of Chapter 1 of Part 1 of
21 Division 3 of Title 2 of the Government Code, shall apply to all
22 meetings of the ICOC, except as otherwise provided in this
23 section. The ICOC shall award all grants, loans, and contracts in
24 public meetings and shall adopt all governance, scientific,
25 medical, and regulatory standards in public meetings.

26 (3) The ICOC may conduct closed sessions as permitted by the
27 Bagley-Keene Open Meeting Act, under Section 11126 of the
28 Government Code. In addition, the ICOC may conduct closed
29 sessions when it meets to consider or discuss:

30 (A) Matters involving information relating to patients or
31 medical subjects, the disclosure of which would constitute an
32 unwarranted invasion of personal privacy.

33 (B) Matters involving confidential intellectual property or
34 work product, whether patentable or not, including, but not
35 limited to, any formula, plan, pattern, process, tool, mechanism,
36 compound, procedure, production data, or compilation of
37 information, which is not patented, which is known only to
38 certain individuals who are using it to fabricate, produce, or
39 compound an article of trade or a service having commercial

1 value and which gives its user an opportunity to obtain a business
2 advantage over competitors who do not know it or use it.

3 (C) Matters involving prepublication, confidential scientific
4 research or data.

5 (D) Matters concerning the appointment, employment,
6 performance, compensation, or dismissal of institute officers and
7 employees. Action on compensation of the institute's officers and
8 employees shall only be taken in open session.

9 (4) The meeting required by paragraph (2) of subdivision (b)
10 of Section 125290.20 shall be deemed to be a special meeting for
11 the purposes of Section 11125.4 of the Government Code.

12 (e) Public Records

13 (1) The California Public Records Act, Article 1 (commencing
14 with Section 6250) of Chapter 3.5 of Division 7 of Title 1 of the
15 Government Code, shall apply to all records of the institute,
16 except as otherwise provided in this section.

17 (2) Nothing in this section shall be construed to require
18 disclosure of any records that are any of the following:

19 (A) Personnel, medical, or similar files, the disclosure of
20 which would constitute an unwarranted invasion of personal
21 privacy.

22 (B) Records containing or reflecting confidential intellectual
23 property or work product, whether patentable or not, including,
24 but not limited to, any formula, plan, pattern, process, tool,
25 mechanism, compound, procedure, production data, or
26 compilation of information, which is not patented, which is
27 known only to certain individuals who are using it to fabricate,
28 produce, or compound an article of trade or a service having
29 commercial value and which gives its user an opportunity to
30 obtain a business advantage over competitors who do not know it
31 or use it.

32 (C) Prepublication scientific working papers or research data.

33 (f) Competitive Bidding

34 (1) The institute shall, except as otherwise provided in this
35 section, be governed by the competitive bidding requirements
36 applicable to the University of California, as set forth in Article 1
37 (commencing with Section 10500) of Chapter 2.1 of Part 2 of
38 Division 2 of the Public Contract Code.

39 (2) For all institute contracts, the ICOC shall follow the
40 procedures required of the Regents by Article 1 (commencing

with Section 10500) of Chapter 2.1 of Part 2 of Division 2 of the Public Contract Code with respect to contracts let by the University of California.

(3) The requirements of this section shall not be applicable to grants or loans approved by the ICOC.

(4) Except as provided in this section, the Public Contract Code shall not apply to contracts let by the institute.

(g) Conflicts of Interest

(1) The Political Reform Act, Title 9 (commencing with Section 81000) of the Government Code, shall apply to the institute and to the ICOC, except as provided in this section and in subdivision (e) of Section 125290.50.

(A) No member of the ICOC shall make, participate in making, or in any way attempt to use his or her official position to influence a decision to approve or award a grant, loan, or contract to his or her employer, but a member may participate in a decision to approve or award a grant, loan, or contract to a nonprofit entity in the same field as his or her employer.

(B) A member of the ICOC may participate in a decision to approve or award a grant, loan, or contract to an entity for the purpose of research involving a disease from which a member or his or her immediate family suffers or in which the member has an interest as a representative of a disease advocacy organization.

(C) The adoption of standards is not a decision subject to this section.

(2) Service as a member of the ICOC by a member of the faculty or administration of any system of the University of California shall not, by itself, be deemed to be inconsistent, incompatible, in conflict with, or inimical to the duties of the ICOC member as a member of the faculty or administration of any system of the University of California and shall not result in the automatic vacation of either such office. Service as a member of the ICOC by a representative or employee of a disease advocacy organization, a nonprofit academic and research institution, or a life science commercial entity shall not be deemed to be inconsistent, incompatible, in conflict with, or inimical to the duties of the ICOC member as a representative or employee of that organization, institution, or entity.

1 (3) Section 1090 of the Government Code shall not apply to
2 any grant, loan, or contract made by the ICOC except where both
3 of the following conditions are met:

4 (A) The grant, loan, or contract directly relates to services to
5 be provided by any member of the ICOC or the entity the
6 member represents or financially benefits the member or the
7 entity he or she represents.

8 (B) The member fails to recuse himself or herself from
9 making, participating in making, or in any way attempting to use
10 his or her official position to influence a decision on the grant
11 loan or contract.

12 (h) Patent Royalties and License Revenues Paid to the State of
13 California

14 The ICOC shall establish standards that require that all grants
15 and loan awards be subject to intellectual property agreements
16 that balance the opportunity of the State of California to benefit
17 from the patents, royalties, and licenses that result from basic
18 research, therapy development, and clinical trials with the need to
19 assure that essential medical research is not unreasonably
20 hindered by the intellectual property agreements. *All revenues*
21 *derived from patents, royalties, and licenses paid to the state as a*
22 *result of intellectual property agreements entered into pursuant*
23 *to this subdivision shall be deposited into the General Fund.*

24 (i) Preference for California Suppliers

25 The ICOC shall establish standards to ensure that grantees
26 purchase goods and services from California suppliers to the
27 extent reasonably possible, in a good faith effort to achieve a
28 goal of more than 50 percent of such purchases from California
29 suppliers.